

45. A method of modulating seed oil content in a plant, the method comprising:
providing a first plant comprising a recombinant expression cassette containing an ADC nucleic acid linked to a plant promoter, which ADC nucleic acid comprises a nucleic acid sequence at least about 80% identical to a nucleic acid sequence selected from a group consisting of SEQ ID NO:100, SEQ ID NO:101, SEQ ID NO:102, SEQ ID NO:103, SEQ ID NO:104, SEQ ID NO:105, SEQ ID NO:106, SEQ ID NO:107, SEQ ID NO:108, SEQ ID NO:109, SEQ ID NO:110, and SEQ ID NO:111, and which ADC nucleic acid encodes a polypeptide that modulates seed mass or oil content;
selfing the first plant or crossing the first plant with a second plant, thereby producing a plurality of seeds; and
selecting seed with altered oil content.

REMARKS

After entry of this amendment, claims 1-4, 6-14, 16-25, 27-35, 37, 40, and 45-109 are pending in the present application. Applicants note with appreciation that the Examiner has indicated that claims 5, 15, 26, 36, 41, and 46-109 are allowable. The Examiner has rejected claims 1-4, 6-14, 16-25, 27-35, 37, 40, and 45 under 35 U.S.C. §112, first paragraph, for allegedly lacking written description in the specification.

To expedite prosecution, applicants have amended the pending claims to approximately the same scope as the allowable claims. The allowable claims are directed to methods, seeds, transgenic plants, or isolated nucleic acids comprising the exemplified sequences. The pending claims are directed to sequences that are at least about 80% identical to the exemplified sequences, except SEQ ID NO: 3, which is claimed in US Patent No. 5,994,622. Support for the new claim limitations is found, for example, on page 7, lines 12-17. Applicants explicitly reserve the right to pursue the original claims in one or more subsequent applications. In addition, claim 1 has been amended to clarify that both seed mass and oil content can be modulated using the nucleic acids of the invention. This amendment introduces no new matter to the claims.

Citing *University of California v. Eli Lilly* 43 USPQ2d 1398 (Fed. Cir. 1997), the Examiner asserts that the present disclosure does not provide adequate written description for the genus, as originally claimed. The rejection is summarized at the top of page 6 of the Office Action.

Briefly, the Examiner asserts that because the genus is defined by partial structure (*i.e.* the presence of an AP2 domain), the claims encompass genes “yet to be discovered”, as well as fragments and fusions of the exemplified sequences. The Examiner further alleges that there is a lack of correlation between structure and function of the claimed sequences. As explained below, such a rejection is entirely improper with respect to the present claims.

An objective standard for determining compliance with the written description requirement is “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *In re Gosteli*, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). In the present case, the Examiner acknowledges that the twelve exemplified sequences and their use to control seed properties are allowable. The only concern, therefore, is whether one of skill would recognize that the inventors had invented the use of nucleic acids that are at least about 80% identical to the exemplified sequences. The specification specifically discusses well known methods for isolating nucleic acid sequences of the invention. In particular, the AP2 domain from the AP2 gene (SEQ ID NO: 3) was used as a probe to identify all of the exemplified sequences (*see, e.g.*, Example 4, Results, page 36). Exemplary sequences identified in this way were tested and shown to be useful in modulating fatty acid content, in the same manner as AP2 (*see*, Example 5). In addition, the specification provides detailed disclosure of PCR primers and PCR conditions by which the for amplifying the desired sequences (*see*, pages 13-16). One of skill would therefore recognize that that a range modifications to the exemplified sequences (in this case up to 20% modification) could be made that would not substantially affect the activity of the encoded proteins. Moreover, as explained below, testing these variants is well within the skill of the art. Thus, in light of the large number of exemplified sequences and well known methods for making and testing nucleic acids within the scope of the pending claims, applicants respectfully submit that the pending claims meet the written description requirement of 35 U.S.C. § 112, first paragraph.

The rejection appears to be based, at least in part, on a concern that one of skill would not be able to make and use nucleic acids within the scope of the claims. Again, applicants believe this requirement of the patent statute is fully met by the pending claims.

It is well established that the proper test of enablement is “whether one skilled in the art could make or use the claimed invention from the disclosure in the patent coupled with information known in the art without undue experimentation.” *United States v. Teletronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988); *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988); MPEP § 2164.01.

Thus, to maintain this rejection, the Examiner must explain why making and testing nucleic acids within the scope of the claims would require undue experimentation.


Identifying nucleic acids which encode proteins with AP2 activity and are at least about 80% identical to the exemplified sequences is entirely routine, given the state of the art and the ample guidance in the specification. As noted above, methods for modification of nucleic acid sequences were well known at the time of the invention. In addition, methods for isolating desired sequences, incorporating them into a recombinant expression cassette, transforming plant cells, and regenerating whole plants are all well known in the art and are also explicitly described in the application (*see*, page 19, line 23 to page 22, line 31). Protocols for testing the sequences for seed mass, seed protein content and seed oil content are also provided in the specification (*see, e.g.*, page 23, line 18 to 24, Example 3, and Example 5). In the absence of reasoning or evidence that any of the above steps were difficult to carry out at the time of the invention, a rejection based on an assertion of undue experimentation cannot be maintained.

Clearly, in view of the above evidence regarding the ease of testing for AP2 function, as well as the acknowledgment that the exemplified sequences are allowable, the Examiner cannot properly assert that the present claims lack written description or that undue experimentation would be required to practice the claimed invention. Withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,


Kevin Bastian
Reg. No. 34,774

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: (415) 576-0200
Fax: (415) 576-0300
KLB
SF 1242744 v1

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. A method of modulating seed mass or oil content in a plant, the method comprising:

providing a first plant comprising a recombinant expression cassette containing an ADC nucleic acid linked to a plant promoter, which ADC nucleic acid [encodes a polypeptide comprising an AP2 domain which is at least 35% identical to SEQ ID NO:4 or SEQ ID NO:5] comprises a nucleic acid sequence at least about 80% identical to a nucleic acid sequence selected from a group consisting of SEQ ID NO:100, SEQ ID NO:101, SEQ ID NO:102, SEQ ID NO:103, SEQ ID NO:104, SEQ ID NO:105, SEQ ID NO:106, SEQ ID NO:107, SEQ ID NO:108, SEQ ID NO:109, SEQ ID NO:110, and SEQ ID NO:111, and which ADC nucleic acid encodes a polypeptide that modulates seed mass or oil content;

selfing the first plant or crossing the first plant with a second plant, thereby producing a plurality of seeds; and

selecting seed with altered mass or oil content.

24. A seed comprising a recombinant expression cassette containing an ADC nucleic acid, which ADC nucleic acid [encodes a polypeptide comprising an AP2 domain which is at least 35% identical to SEQ ID NO:4 or SEQ ID NO:5] comprises a nucleic acid sequence at least about 80% identical to a nucleic acid sequence selected from a group consisting of SEQ ID NO:100, SEQ ID NO:101, SEQ ID NO:102, SEQ ID NO:103, SEQ ID NO:104, SEQ ID NO:105, SEQ ID NO:106, SEQ ID NO:107, SEQ ID NO:108, SEQ ID NO:109, SEQ ID NO:110, and SEQ ID NO:111, and which ADC nucleic acid encodes a polypeptide that modulates seed mass or oil content, with the proviso that the seed is not from Arabidopsis.

35. A transgenic plant comprising an expression cassette containing a plant promoter operably linked to a heterologous ADC [polynucleotide] nucleic acid, wherein the ADC [polynucleotide] encodes a polypeptide comprising an AP2 domain which is at least 35% identical to SEQ ID NO:4 or SEQ ID NO:5] nucleic acid comprises a nucleic acid sequence at least about 80% identical to a nucleic acid sequence selected from a group consisting of SEQ ID NO:100, SEQ ID NO:101, SEQ ID NO:102, SEQ ID NO:103, SEQ ID NO:104, SEQ ID NO:105, SEQ ID NO:106,

SEQ ID NO:107, SEQ ID NO:108, SEQ ID NO:109, SEQ ID NO 110, and SEQ ID NO:111, and which ADC nucleic acid encodes a polypeptide that modulates seed mass or oil content, with the proviso that the transgenic plant is not Arabidopsis.

40. An isolated nucleic acid molecule comprising an expression cassette containing a plant promoter operably linked to a heterologous ADC [polynucleotide, wherein the ADC polynucleotide encodes a polypeptide comprising an AP2 domain which is at least 95% identical to SEQ ID NO:4 or SEQ ID NO:5] nucleic acid comprises a nucleic acid sequence at least about 80% identical to a nucleic acid sequence selected from a group consisting of SEQ ID NO:100, SEQ ID NO:101, SEQ ID NO:102, SEQ ID NO:103, SEQ ID NO:104, SEQ ID NO:105, SEQ ID NO:106, SEQ ID NO:107, SEQ ID NO:108, SEQ ID NO:109, SEQ ID NO 110, and SEQ ID NO:111, and which ADC nucleic acid encodes a polypeptide that modulates seed mass or oil content[, with the proviso that the isolated nucleic acid is not SEQ ID NO: 3].

45. A method of modulating seed oil content in a plant, the method comprising:
providing a first plant comprising a recombinant expression cassette containing an ADC nucleic acid linked to a plant promoter, which ADC nucleic acid [encodes a polypeptide comprising an AP2 domain which is at least 35% identical to SEQ ID NO:4 or SEQ ID NO:5] comprises a nucleic acid sequence at least about 80% identical to a nucleic acid sequence selected from a group consisting of SEQ ID NO:100, SEQ ID NO:101, SEQ ID NO:102, SEQ ID NO:103, SEQ ID NO:104, SEQ ID NO:105, SEQ ID NO:106, SEQ ID NO:107, SEQ ID NO:108, SEQ ID NO:109, SEQ ID NO 110, and SEQ ID NO:111, and which ADC nucleic acid encodes a polypeptide that modulates seed mass or oil content;

selfing the first plant or crossing the first plant with a second plant, thereby producing a plurality of seeds; and

selecting seed with altered oil content.